

## REMARKS

The docket number for this application has changed from “ANTH-0004” to “9516-495-999”. Please reference docket number 9516-495-999 in the future.

Claims 1-6, 8, 9, 12, 13, 15-18, 20-23, 31, 32, 34-37 and 50 are pending in the present application. Claims 1, 18, 31, 34 and 50 are amended herein. Support for the amendments to these claims are found in the claims as originally filed, and in the specification at least at paragraphs [0022] and [0041]. Upon entry of these amendments, claims 1, 3, 5, 6, 8, 12, 13, 15-18, 20-23, 31, 32, 34-37 and 50 will be pending in the application.

### The Obviousness-Type Double Patenting Rejection

The Examiner has provisionally rejected claims 1, 3, 5, 6 and 18 on the ground of Nonstatutory obviousness-type double patenting as unpatentable over claims 1, 2, 10, 13 and 14 of copending Application No. 10/366,671 in view of the abstract of Erices *et al.*, *Br. J. Haematol.* 109(1):235-242 (2000). Office Action at pages 2-5. Applicant requests that the rejection be held in abeyance until one set of claims is deemed to be in condition for allowance.

### The Rejections Under 35 U.S.C. § 102 Should Be Withdrawn

The Examiner has rejected claims 1, 3, 5, 6, 8, 15-18, 20-23, 31, 32, 34, 36, 37 and 50 under 35 U.S.C. § 102(b) as anticipated by Fasouliotis *et al.*, *Eur. J. Obstet. Gynecol. Reprod. Biol.* 90:13-25 (2000) (“Fasouliotis”). Office Action at pages 5-10. Applicant respectfully traverses as follows.

The Examiner contends that Fasouliotis teaches a cytotherapeutic unit comprising cells from cord blood and cells from placental perfusate in that Fasouliotis allegedly teaches collecting umbilical cord blood and teaches flushing the placenta with saline and retrieving blood by syringe. Office Action at page 6 (citing Fasouliotis p. 15, right column, and Table 2). Without conceding the propriety of the Examiner’s rejection, Applicant has amended claims 1, 18, 31, 34 and 50 to recite that the cytotherapeutic unit comprises potent CD34<sup>-</sup>OCT-4<sup>+</sup> cells that have been isolated from placental perfusate. At most, Fasouliotis ostensibly teaches the collection of *cord blood* by a method that includes flushing of a placenta with saline to retrieve additional blood. Fasouliotis does not teach the separation of potent CD34<sup>-</sup>OCT-4<sup>+</sup> cells from perfusate, and therefore fails to teach a cytotherapeutic unit that comprises CD34<sup>-</sup>OCT-4<sup>+</sup> cells *isolated* from placental perfusate. Moreover, to the extent Fasouliotis teaches the separation of CD34<sup>+</sup> cells from cord blood, Fasouliotis teaches the production of a cytotherapeutic unit that excludes potent CD34<sup>-</sup>OCT-4<sup>+</sup> cells, as required by the amended claims. Fasouliotis therefore

does not teach a cytotherapeutic unit comprising cells from a *plurality* of sources. Thus, for the above reasons Fasouliotis fails to teach a cytotherapeutic unit according to the claims.

Fasouliotis also fails to teach the cytotherapeutic unit of claim 18, which requires at least two *preselected* types of potent cells from a plurality of sources. Fasouliotis only teaches the collection of cord blood, and the separation of CD34<sup>+</sup>, CD45RA<sup>+</sup> or CD71<sup>+</sup> cells from cord blood. However, separation of these cells from cord blood would exclude potent CD34<sup>+</sup>OCT-4<sup>+</sup> cells as required by claim 18. As such, Fasouliotis does not anticipate claim 18 as amended.

Thus, Fasouliotis does not anticipate the claims as amended. Applicant respectfully requests that the Examiner withdraw this rejection of the claims.

#### The Rejections Under 35 U.S.C. § 103 Should Be Withdrawn

The Examiner has rejected the claims under 35 U.S.C. § 103 as allegedly obvious over several combinations of references. Applicant addresses each combination below.

A combination of prior art references cannot render a claim obvious unless the PTO provides evidence that the combination of references meet a three-part test for *prima facie* obvious. First, the prior art reference or references must provide “motivation, suggestion, or teaching of the desirability of making the specific combination that was made by the applicant.” See *In re Kotzab*, 217 F.3d 1365, 1370, 55 U.S.P.Q.2d 1313, 1316 (Fed. Cir. 2000); *Princeton Biochemicals, Inc. v. Beckman Coulter, Inc.*, 411 F.3d 1332, 1337, 75 U.S.P.Q.2d 1051, 1054 (Fed. Cir. 2005). Second, the prior art references cited by the PTO must suggest to one of ordinary skill in the art that the invention would have a reasonable expectation of success. See *In re Dow Chemical*, 837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1532 (Fed. Cir. 1988); *Boehringer Ingelheim Vetmedica, Inc.*, 320 F.3d 1339, 1354, 65 U.S.P.Q.2d 1961, 1971 (Fed. Cir. 2003); *Noelle v. Lederman*, 355 F.3d 1343, 1352, 69 U.S.P.Q.2d 1508, 1516 (Fed. Cir. 2004). Finally, the PTO must show that the prior art references, either alone or in combination, teach or suggest each and every limitation of the rejected claims. See *Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d 1461, 1473, 43 U.S.P.Q.2d 1481, 1490 (Fed. Cir. 1997); *Litton Systems, Inc. v. Honeywell, Inc.*, 87 F.3d 1559, 1569, 39 U.S.P.Q.2d 1321, 1327 (Fed. Cir. 1996).

#### *The Rejections Over Pykett and Fasouliotis Should Be Withdrawn*

The Examiner has rejected claims 1, 3, 5, 6, 8, 12, 15-18, 20-23, 31, 32, 34-37 and 50 under 35 U.S.C. § 103 as allegedly obvious over the combination of Pykett *et al.*, U.S. Patent

No. 6,548,299 ("Pykett") in view of Fasouliotis. Office Action at pages 16. Applicant traverses as follows.

The Examiner contends that Pykett teaches, *inter alia*, a population of cells from blood comprising, *e.g.*, CD34<sup>+</sup> cells, which may be obtained from bone marrow, peripheral blood, umbilical cord blood, placental blood, fetal liver or lymphoid soft tissue. The Examiner states that Pykett does not teach that a source of hematopoietic cells is a postpartum mammalian placenta. Office Action at page 14. The Examiner relies on Fasouliotis for the teachings missing in Pykett, specifically the alleged teaching in Fasouliotis of using saline to collect more cord blood from a placenta.

As noted above, Applicant has amended claims 1, 18, 31, 34 and 50 to require that the recited cytotherapeutic unit comprise cells that are *isolated* from placental perfusate, where the cells are potent CD34<sup>+</sup>OCT-4<sup>+</sup> cells. Pykett does not teach or suggest a cytotherapeutic unit that comprises such potent cells. As explained above, Fasouliotis also does not teach or suggest such cells, let alone a cytotherapeutic unit comprising such cells, and therefore does not remedy the deficiencies of Pykett. Thus, the combination of Pykett and Fasouliotis does not teach or suggest the cytotherapeutic units, comprising the specified cells, in the claims as amended. As such, a person of ordinary skill in the art would not combine Pykett and Fasouliotis to produce the cytotherapeutic units or libraries of claims 1, 18, 31, 34 and 50, and, as a result, the cited references do not render the amended claims obvious. As the remaining rejected claims depend ultimately from these claims, the cited references also do not render the remaining claims obvious.

For the above reasons, Applicant respectfully requests that the Examiner withdraw this rejection of the claims.

*The Rejections Over Pykett and Wang Should Be Withdrawn*

The Examiner has rejected claims 1, 3, 5, 6, 8, 12, 15-18, 20-23, 31, 32, 34-37 and 50 under 35 U.S.C. § 103 as allegedly obvious over the combination of Pykett and Wang *et al.*, *Blood* 98(11 Part 1) 193, Abstract 769 (2001). Office Action at pages 16-17. Applicant traverses as follows.

The Examiner contends that Pykett teaches, *inter alia*, a population of cells from blood comprising, *e.g.*, CD34<sup>+</sup> cells, which may be obtained from bone marrow, peripheral blood, umbilical cord blood, placental blood, fetal liver or lymphoid soft tissue. The Examiner states that Pykett does not teach that a source of hematopoietic cells is a postpartum mammalian placenta. Office Action at page 16. The Examiner contends that Wang teaches methods of

recovering hematopoietic progenitor and stem cells (HPSC), including CD34<sup>+</sup> cells, from placenta by perfusing, and that Wang concludes that HPSC from postpartum placenta may be used to supplement umbilical cord blood.

As noted above, claims 1, 18, 31, 34 and 50 have been amended to specify that the recited cytotherapeutic units comprise potent CD34<sup>-</sup>OCT-4<sup>+</sup> cells. As explained above, Pykett does not teach or suggest such cells, or cytotherapeutic units comprising such cells. Likewise, Wang does not teach or suggest potent CD34<sup>-</sup>OCT-4<sup>+</sup> cells, or cytotherapeutic units comprising such cells. Thus, the combination of Pykett and Wang fails to teach all of the limitations of the claims as amended. As such, a person of ordinary skill in the art would not combine Pykett and Wang to produce the claimed cytotherapeutic units, and, as a result, the cited references do not render claims 1, 18, 31, 34 and 50 obvious. As the remaining rejected claims depend ultimately from these claims, the cited references also do not render the remaining claims obvious.

For the above reasons, Applicant respectfully requests that the Examiner withdraw this rejection of the claims.

*The Rejections Over Johnson and Fasouliotis Should Be Withdrawn*

The Examiner has rejected claims 1-6, 8, 15-18, 20-23, 31, 32, 34, 35 and 50 under 35 U.S.C. § 103 as allegedly obvious over the combination of Johnson, U.S. Patent No. 5,677,139 ("Johnson") and Fasouliotis. Office Action at pages 17-21. Applicant traverses as follows.

The Examiner contends that Johnson teaches, *inter alia*, a population of hematopoietic, e.g., CD34<sup>+</sup>, cells from blood products, which may be obtained from bone marrow, peripheral blood, umbilical cord blood, placental blood, fetal liver or lymphoid soft tissue. The Examiner states that Johnson does not teach the use of postpartum placenta perfusate. Office Action at page 20. The Examiner relies on Fasouliotis to provide the teachings and suggestions missing in Johnson.

As noted above, claims 1, 18, 31, 34 and 50 have been amended to specify that the recited cytotherapeutic units comprise potent CD34<sup>-</sup>OCT-4<sup>+</sup> cells that have been isolated from placental perfusate. Johnson does not teach or suggest such cells, and does not teach or suggest a cytotherapeutic unit comprising such cells. As explained above, Fasouliotis also does not teach or suggest such cells. Thus, the combination of Johnson and Fasouliotis fails to teach or suggest a cytotherapeutic unit comprising potent CD34<sup>-</sup>OCT-4<sup>+</sup> cells that have been isolated from placental perfusate as presently claimed. As such, a person of ordinary skill in the art would not combine Johnson and Fasouliotis to produce the presently-claimed cytotherapeutic

units. The cited combination of references therefore does not render claims 1, 18, 31, 34 or 50 obvious. As the remaining rejected claims depend ultimately from these claims, the cited combination of references also does not render the remaining claims obvious.

For the above reasons, Applicant respectfully requests that the Examiner withdraw this rejection of the claims.

*The Rejections Over Fasouliotis and Ende Should Be Withdrawn*

The Examiner has rejected claims 1, 12 and 13 under 35 U.S.C. § 103 as allegedly obvious over the combination of Fasouliotis and Ende *et al.*, *Life Sci.* 69:1531-1539 (2001) (“Ende”). Office Action at pages 21-23. Applicant traverses as follows.

The Examiner restates the alleged teachings of Fasouliotis from the above rejections, but states that Fasouliotis does not teach a cytotherapeutic unit in which the potent cells are obtained from at least two or at least five individuals. Office Action at page 22. The Examiner contends that Ende teaches pooling of umbilical cord samples to reconstitute bone marrow.

As noted above, however, claim 1 has been amended to specify that the recited therapeutic unit comprises potent CD34<sup>+</sup>OCT-4<sup>+</sup> cells that have been isolated from placental perfusate. As explained above, Fasouliotis does not teach or suggest such cells, or cytotherapeutic units comprising such cells. Ende, which teaches only the use of cord blood, does not teach or suggest such cells, either. Thus, the combination of Fasouliotis and Ende fails to teach or suggest all limitations of the claims as amended, and a person of ordinary skill in the art would not combine Fasouliotis and Ende to produce the cytotherapeutic units of claim 1. Therefore, the combination of Fasouliotis and Ende does not render claim 1 obvious. Because claims 12 and 13 depend from claim 1, the combination fails to render these claims obvious, as well.

For the above reasons, Applicant respectfully requests that the Examiner withdraw this rejection of the claims.

*The Rejection over Johnson and Wang Should Be Withdrawn*

The Examiner has rejected claims 1, 3, 5, 6, 8, 12, 15-18, 20-23, 31, 32, 34-37 and 50 under 35 U.S.C. § 103 as allegedly obvious over the combination of Johnson and Wang. Office Action at page 23-25.

The Examiner, repeating characterizations from earlier in the Office Action, contends that Johnson teaches, *inter alia*, a population of hematopoietic, *e.g.*, CD34<sup>+</sup>, cells from blood products, which may be obtained from bone marrow, peripheral blood, umbilical cord blood,

placental blood, fetal liver or lymphoid soft tissue. The Examiner further contends that Wang teaches methods of recovering hematopoietic progenitor and stem cells (HPSC), including CD34<sup>+</sup> cells, from placenta by perfusing, and that Wang concludes that HPSC from postpartum placenta may be used to supplement umbilical cord blood.

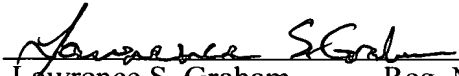
As noted above, claims 1, 18, 31, 34 and 50 have been amended to specify that the recited cytotherapeutic units comprise potent CD34<sup>-</sup>OCT-4<sup>+</sup> cells that have been isolated from placental perfusate. Johnson does not teach or suggest such cells, and does not teach or suggest a cytotherapeutic unit comprising such cells. Likewise, as explained above, Wang does not teach or suggest potent CD34<sup>-</sup>OCT-4<sup>+</sup> cells, or cytotherapeutic units comprising such cells. Thus, the combination of Johnson and Wang fails to teach all of the limitations of the claims as amended. As such, a person of ordinary skill in the art would not combine Johnson and Wang to produce the claimed cytotherapeutic units, and, as a result, the cited references do not render claims 1, 18, 31, 34 and 50 obvious. As the remaining rejected claims depend ultimately from these claims, the cited references also do not render the remaining claims obvious.

### CONCLUSION

Applicant respectfully requests that the present remarks be made of record in the file history of the present application. An early allowance of the application is earnestly requested. The Examiner is invited to contact the undersigned with any questions concerning the application.

Respectfully submitted,

Date: March 28, 2007

  
by: Lawrence S. Graham Reg. No. 49,020  
for: Anthony M. Insogna Reg. No. 35,203

**JONES DAY**  
222 East 41<sup>st</sup> Street  
New York, NY 10017-6702  
(212) 326-3939